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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,064	03/01/2002	Leonard Paul	595-018-1	4642

7590 02/12/2004

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EXAMINER	
THISSELL, JEREMY	
ART UNIT	**PAPER NUMBER**
3763	6

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,064	PAUL, LEONARD	
	Examin r	Art Unit	
	Jeremy T. Thissell	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16-24* is/are pending in the application.

4a) Of the above claim(s) *20-24* is/are withdrawn from consideration.

5)☒ Claim(s) *9-12,16 and 17* is/are allowed.

6)☒ Claim(s) *1-8,13,14,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14 and 16-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14 and 16-19, drawn to a douche system, classified in class 604, subclass 408.

II. Claims 20 and 21, drawn to a cleansing foam, classified in class 424, subclass 405.

III. Claims 22 and 23, drawn to a method of making a douche assembly, classified in class 141, subclass 2.

IV. Claim 24, drawn to a method of using a douche system, classified in class 222, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process since the device may be used for dispensing on surfaces other than skin.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a different process, such as one that does not add a finger actuated valve/cap.

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the compositions are different. The subcombination has separate utility such as as an antimicrobial composition, whereas the combination can be an anesthetic.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product may be used on a location other than skin.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a foam and a method of making a dispensing assembly with a different foam, and therefore the inventions are not usable together. And clearly a foam and a method have different effects.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a method of making and a method of using a dispensing system. The two methods are not usable together, since the method of making must be completed before the method of using may commence. The two inventions have different functions or effects since one results in a system, and the other results in a treatment of a patient.

Newly submitted claims 20-24 are directed to inventions that are independent or distinct from the invention originally claimed for the reasons discussed above.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, **claims 20-24 have been withdrawn from**

consideration as being directed to non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claims 1 and 13 are objected to because of the following informalities:

In Claim 1, line 16, the word "form" should be "from."

In Claim 13, line 19, the word "douce" should be "douche."

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 7, and 8 are rejected under 35 U.S.C. 102(e) as being unpatentable over Fasani (US 6,293,928) in view of Melman (US 5,853,767)

Fasani teaches all the claimed subject matter including the length of the nozzle (col. 3, line 9), except for the exact makeup of the composition. Melman teaches a foaming douche that contains 5% polysorbate 20, and also contains an anesthetic, along with water. See col. 3, line 50; col. 6, lines 18-52. It would have been obvious to one of ordinary skill in the art to use a well-known douche solution such as that of

Melman or components thereof in the device of Fasani, since Fasani is designed to deliver douche compositions.

Claims 1-4, 7, and 8 are rejected under 35 U.S.C. 102(b) as being unpatentable over Packer et al (US 3,968,797) in view of Melman (US 5,853,767).

Packer teaches all the claimed subject matter, including the check valve (col. 7, line 67), except for the exact makeup of the composition. See discussion above regarding Melman.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Packer and Melman as applied to claim 4 above, and further in view of Sneider (US 4,168,032).

Packer as modified by Melman teaches all the claimed subject matter except for the tapered shape of the nozzle. Sneider teaches a tapered nozzle as claimed. It would have been obvious to one of ordinary skill in the art to form the device of Packer with the tapered nozzle of Sneider so as to facilitate use of the device for enemas as well as vaginal douching. Note that Sneider is used for both, and offers differently shaped nozzles for each use.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Packer and Melman as applied to claim 4 above, and further in view of Reddick (US 4,894,053).

Packer as modified by Melman teaches all the claimed subject matter except for having a uniform diameter nozzle. Reddick teaches a douche apparatus having a

nozzle with a uniform diameter as claimed. It would have been obvious to form the nozzle of Packer with a uniform diameter nozzle as in Reddick as an obvious design choice of shape, the uniform diameter offering the advantage of simplified manufacturing.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Packer (or Fasani) and Melman as applied to claim 1 above, and further in view of Van Leuven (US 4,184,974).

Packer (or Fasani) as modified by Melman teaches all the claimed subject matter except for the antimicrobial agent being one of the claimed silver compounds. Van Leuven teaches the use of silver nitrate as an anti-microbial agent in a douche composition. (col. 3, line 8; col. 2, line 46). Again it would have been obvious to use such known douching agents with the device of either Packer or Fasani as discussed above.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Packer (or Fasani) in view of Michaels et al (US 5,314,917), Gartner (US 4,526,751), and Brown-Skrobot et al (US 5,547,985).

Packer (or Fasani) teach all the claimed douche dispenser structure, but do not teach the claimed composition.

Michaels teaches a douche composition having citric acid (col. 6, line 26), nonoxynol-9 (col. 2, line 19) in a range of concentrations, glycerine (col. 6, line 36), fragrance (col. 6, line 37), and purified water (col. 8, line 6).

Gartner teaches a povidone iodine (aka betadine; about 1%, see col. 1, lines 62-63) douche composition and specifies that other additives may be included (col. 2, lines 35-39).

Brown-Skrobot teaches a douche including glyceryl compounds in a range of concentrations, and deionized water.

As can be seen from the aggregate of these references, all of these components are commonly found in douches in varying concentrations. Each has its own beneficial effect that is well-known in the art. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980). In the instant case, without demonstrated criticality of the components and there concentrations, the combination of them into a single douche formulation flows logically from their having been individually taught in the prior art.

Allowable Subject Matter

Claims 9-12, 16, and 17 are allowable over the prior art of record.

As discussed in the previous office action:

> The prior art does not teach the inner and outer diameters claimed in claims 9, 10, and 12. Most of the prior art is silent with regard to the sizing of the nozzle walls. The only disclosure of sizing was found in Fasani, whose sizing was much larger than the claimed dimensions. Additionally, applicant offers criticality of the claimed dimensions with regard to fluid dynamics of the device. Such criticality is discussed on pages 22-23 of the specification.
>
> The prior art also does not teach the claimed valve structure with a cap/disk configuration. Some prior art discloses ball valves, but none have a disk.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

This action is being made Non-final in view of new grounds of rejection.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for all fax communications is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt
February 6, 2004

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